REMARKS

A. Status of the Claims

Claims 182-196 were pending at the time of the Action. Claims 182-196 stand rejected. The specific grounds for rejection and Applicants' response thereto are set forth below.

B. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 182-196 have been rejected under 35 U.S.C. §112, first paragraph, as not being enabled by the specification. The Action acknowledges that the specification is enabling for PAGs 4, 6, 7, 16, 17, 20, and 21; however, the Action asserts that the specification is not reasonably enabling for all PAGs encompassed by the claims. Applicants respectfully traverse the rejection.

In support of the enablement rejection, the Action relies on the disclosure in Roberts *et al.* of a PAG (PAG-1) that reportedly requires at least 3 months post-partum to drop back to threshold values. Applicants note, however, that enablement must be evaluated against the ***claimed*** invention (MPEP § 2164.08), which is directed to PAGs that are present early in pregnancy and are ***undetectable at about two months post-partum***. A PAG that requires 3 months post-partum to return to threshold levels does not fall within the scope of the claims, and thus is not relevant to the enablement of the claims. The Action itself notes that the PAG-1 taught by Robert *et al.* is outside the scope of the claims (Action, p. 3, ln. 6-10). Withdrawal of the rejection is, therefore, respectfully requested.

Applicants further note that the Declaration of Dr. Jonathan A. Green filed with Applicants previous response dated September 20, 2004 provided data demonstrating enablement for the full scope of the claimed invention. In particular, the Declaration of Dr.

Green described studies demonstrating that PAGs 4, 6, 7, 16, 17, 20 and 21 are indicators of pregnancy undetectable by about two-months post-partum (Declaration of Jonathan A. Green, ¶ 14). The demonstration of enablement for PAGs 4, 6, 7, 16, 17, 20, and 21 constitutes well more than a representative number of PAGs encompassed by the present claims. Applicants need only provide one method for making and using the claimed invention with a reasonable correlation to the entire scope of the claims (MPEP §2164.01(b)). Applicants have more than met this standard.

Moreover, Applicants provide a second Declaration of Jonathan A. Green ("2nd Declaration of Dr. Green") (Appendix A), as additional evidence that a person of ordinary skill in the art would be able to isolate and identify additional PAGs that are present early in pregnancy and are undetectable at about two months post-partum with only routine experimentation. In particular, Dr. Green demonstrates that the specification fully describes the assays and procedures that would be used by one of skill in the art to isolate additional PAGs within the scope of the claims and explains that following the procedures in the specification would require only routine experimentation to obtain such PAGs.

For example, the 2nd Declaration of Dr. Green identifies the portions of the specification that teach the procedures a person of ordinary skill in the art would use to identify PAGs that are detectable early in pregnancy and are undetectable at about two months post-partum in addition to PAGs 4, 6, 7, 16, 17, 20, and 21. In paragraph 6, Dr. Green states that one approach taught in the present specification for isolating and identifying such additional PAGs is to clone PAGs by cDNA library screening or RT-PCR from mRNA obtained from early-pregnancy placentas using the PAG-encoding sequences and fragments disclosed in the present specification. The resulting cDNAs are translated and the polypeptides used for antibody production as taught by the

specification at page 42, lines 19-21 (2nd Declaration of Dr. Green, ¶ 6). The monoclonal or polyclonal antibodies are then used to screen serum or other biological fluids to identify the PAGs that are detectable early in pregnancy and undetectable at about two months post-partum (2nd Declaration of Dr. Green, ¶ 6). The present specification describes methods for the immunological detection of pregnancy at, for example, page 50, line 11 to page 55, line 27 (2nd Declaration of Dr. Green, ¶ 6).

As a further example, the 2nd Declaration of Dr. Green explains that another approach taught by the present specification for isolating and identifying additional PAGs is to employ an antibody to a known PAG (2nd Declaration of Dr. Green, ¶ 7). For example, as described in the specification, an anti-PAG antibody may be used in an antibody cloning protocol to obtain cDNA or genes encoding other PAG polypeptides (Specification, p. 46, ln. 2-12) (2nd Declaration of Dr. Green, ¶ 7). The resulting cDNAs are translated and the recombinant proteins used for antibody production as taught by the specification at page 42, lines 19-21 (2nd Declaration of Dr. Green, ¶ 7). The monoclonal or polyclonal antibodies are then used to screen serum or other biological fluids to identify the PAGs that are detectable early in pregnancy and undetectable at about two months post-partum (2nd Declaration of Dr. Green, ¶ 7). The present specification describes methods for the immunological detection of pregnancy at, for example, page 50, line 11 to page 55, line 27 (2nd Declaration of Dr. Green, ¶ 7).

In conclusion, Dr. Green notes that, by following the teachings of the present specification outlined above, a person of ordinary skill in biochemistry and reproductive biology would be able to identify a bovine PAG that is detectable early in pregnancy and undetectable about two months post-partum using only routine methods described in the specification. (2nd Declaration of Dr. Green, ¶ 8).

In view of the foregoing, it is submitted that enablement for the full scope of the claims has been established. Removal of the rejection is therefore respectfully requested.

C. Rejection Under 35 U.S.C. §112, Second Paragraph

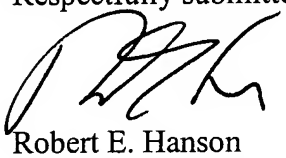
The Action rejects claims 182-192 under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Action asserts that the recitation "present early in pregnancy" is vague and indefinite because it is not clear how "early" PAG can be detected. Applicants traverse this rejection.

As described throughout the specification, "early" pregnancy refers to a period prior to about day 30 of pregnancy (*see e.g.,* Specification, p. 5, ln. 8-9; p. 5, ln. 20-22; p. 8, ln. 1-5; p. 8, ln. 9-12; and p. 24, ln. 11-14). For example, the specification states that "[b]y virtue of their early expression, these PAGs can be detected by conventional immunological techniques in physiological fluids of heifers or cows (especially in serum, urine, and milk) to detect the presence of a fetus or fetuses in the uterus prior to day 30 of pregnancy." (p. 24, ln. 11-14). This is a discrete time period, and thus there is no indefiniteness in the recitation of the term. In view of the disclosure in the specification, Applicants submit that it is reasonably clear to a person of ordinary skill in the art how "early" PAG can be detected. Removal of the rejection is therefore respectfully requested.

D. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and a notification to that effect is earnestly solicited. Should the Examiner have any questions regarding this response, a telephone call to the undersigned in invited.

Respectfully submitted,



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APPENDIX A